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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,287	02/19/2004	Jei-Fu Shaw	70002-104001	4293

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
08/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/782,287	SHAW ET AL.	
	Examiner	Art Unit	
	TAEYOON KIM	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-36 and 45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-36 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment and response filed on Apr. 16, 2009 has been received and entered into the case.

Claims 1-13, 17, 21-30, 37-44, 51 and 52 have been canceled, and claims 14-16, 18-20, 31-36 and 45-50 are pending and have been considered on the merits. All arguments have been fully considered.

It is noted that applicant reinstated the previously deleted limitation in claim 16. Since applicant elected wine as a species according to the response filed on 8/23/2006, the species other than wine listed in claim 16 are withdrawn.

The claim rejection under 35 U.S.C.§112, 1st par., has been withdrawn due to the amendment.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In the response to the previous office action, applicant alleged that the current claims covers a method of producing a fermentation product from a starch-containing produce, including a dual-enzyme digestion process to produce a glucose-rich syrup and a subsequent fermentation process of growing a microorganism in the glucose-rich syrup to produce a fermentation product. Applicant further asserted that the method requires that the glucose-rich syrup obtained from the dual-enzyme digestion process be "used directly" for growing a microorganism.

In response to applicant's argument that the references fail to show certain features of

applicant's invention, it is noted that the features upon which applicant relies (i.e., the glucose-rich syrup being used directly) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further alleged that a person of ordinary skill in the art would have known that only sugar cannot be used directly to grow a microorganism as it lacks other nutrient sources necessary for microorganism growth. This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

It is noted that the specification of the current invention does not disclose any teaching of using glucose-rich syrup without any other nutrients (e.g. a nitrogen source). Rather, the specification discloses that the glucose-rich syrup can be used to produce rice wine directly (p.4), and it is construed that the meaning of "directly" in the context is as the glucose-rich syrup being without further treatment (e.g. treatment with glucose isomerase to obtain fructose-rich syrup) as disclosed in the specification. Nowhere in the specification indicates that the meaning of "directly" is interpreted as without any other nutrients.

Applicant also argued that the cited references do not teach the newly introduced

limitations in claim 45, and further alleged that the yield of 10.5% ethanol in 3 days, or 13.5% in 5 days obtainable from the method of the current invention is unexpected or unpredictable improvement in view of the prior art.

Again it is acknowledged that the prior art cited in the previous office action do not teach the limitation of particular yield of ethanol. The specification discloses that the glucose concentration at around 105 mg/ml yielded 10.5% ethanol after fermentation in 3 days, and 13.5% ethanol after 5 days, and concluded that it is unexpected compared to the 1 % of ethanol produced from glucose concentration of 11 mg/ml (p.7, lines 21-24). If the conversion of glucose to ethanol is proportional, it is assumed that approximately 10 times (11 mg/ml vs. 105 mg/ml) as much as the glucose would increase about 10 fold ethanol concentration. Then, it is expected that about 10% of ethanol can be obtained from 105 mg/ml of glucose under the same condition as being used for 11 mg/ml of glucose fermentation. This cannot be considered unexpected since the expected yield (10%) is not significantly different from the claimed yield (10.5 - 13.5%).

As discussed in the previous office action (see p.8-9 of OA on 1/9/2009), the argument on the ethanol yield based on Skory et al. is not persuasive.

Applicant argued that the percentage of ethanol produced in a 6-day fermentation period according to Skory et al. is 1.59-2.44%, which is far less than the claimed percentage of 10.5% or 13.5%. The argument is fully considered but not persuasive because applicant's argument is against the individual references, rather then the references in combination, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The teaching of Skory et al. combined with the teaching of Seidman et al. is the use of A. oryzae for the ethanol Fermentation process using the glucose-rich solution of Seidman et al. Although Skory et al. disclose the yield of ethanol, it is not based on the method of Seidman et al. Seidman et al. teach a method to produce glucose-rich solution or syrup as the claimed in the current invention. While Skory et al. disclose the use of glucose as a substrate for the fermentation process, the pure glucose used in the method of Skory et al. is different from the glucose-rich solution of Seidman et al. in their concentration. Like the glucose-rich syrup claimed in the instant application, the dextrose-rich solution of Seidman et al. is not purely glucose solution. It contains other partially hydrolyzed polysaccharides along with dextrose/glucose. Therefore, even if the yield of Skory et al. is compared to the ethanol yield of the current invention, there is significant difference in the concentration of carbon sources utilized for fermentation between the method of Skory et al. and the claimed method.

Unless the glucose-rich syrup of the claimed invention is a product of "complete hydrolysis" of starch to glucose without having any incomplete intermediate products, it is considered to comprise not only glucose but also other in complete hydrolysis products. It is well known in the art that α-amylases hydrolyze alpha-1, 4-glycosidic linkages, randomly yielding dextrins, oligosaccharides and monosaccharides, and glucoamylases decompose starch into glucose by tearing-off glucose units from the non-reduced end of the polysaccharide chain. Upon the hydrolysis of starch material with these two enzymes sequentially as claimed in the current invention, unless the conversion of starch to glucose is complete, a person of ordinary skill in the art would clearly expect that the hydrolysates of starch material would contain various different species of intermediate products. Therefore, these incomplete intermediate products present in

the glucose-rich syrup serve additional glucose source during the fermentation process considering microorganisms such as Aspergillus oryzae producing and secreting glucoamylases during the fermentation process, and thus it is expected that overall ethanol production from the glucose-rich syrup with 105-114 mg/ml of glucose would be significantly higher than the ethanol production solely based on 100 mg/ml of glucose as taught by Skory et al. Therefore, it cannot be considered that the method claimed in the current invention produces unexpected and surprising results.

Furthermore, as Skory et al. discloses, the yield of ethanol from 50 g/l of glucose by fermenting with A. oryzae NRRL 694 is nearly 100% of theoretical yield (p.204, Results and discussion). Considering the ethanol yield of the current claim being at best 100% or less of the theoretical yield, the strain of Skory et al. is capable of producing the comparable amount of ethanol under the same condition as the claimed invention. Since the method steps and materials used in the method of Seidman et al. in view of Skory et al. is substantially similar, if not identical, and A. oryzae strain of Skory et al. is capable of nearly 100% of theoretical yield, a person of ordinary skill in the art would have expected that the method of Seidman et al. in view of Skory et al. is capable to produce the substantially similar, if not identical, yields in ethanol/wine production.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 45 discloses a concentration of glucose being 105-114 mg/ml, and the fermentation process with Aspergillus oryzae yields 10.5% ethanol in 3 days or 13.5% ethanol in 5 days.

The specification shows an example (Example 4) wherein the glucose concentration in the glucose-rich syrup being 105 mg/ml, which yielded 10.5% of ethanol in 3 days or 13.5% of ethanol in 5 days by fermentation with Aspergillus oryzae (p.7).

However, there is no disclosure of the range of glucose concentration (i.e. 105-114 mg/ml) in the specification, and the only disclosure of 114 mg/ml is in Example 1 (p.6, lines 11-12). It is not disclosed that the range of 105-114 mg/ml of glucose in the glucose-rich syrup yielded 10.5% or 13.5% of ethanol in 3 days or 5 days, respectively. Therefore, it is considered the current amendment introduced a new matter to the instant application.

Furthermore, claim 14 generically discloses first and second starch hydrolyzing enzymes without specific type of enzymes whereas the specific glucose concentration (i.e. 105-114 mg/ml) and the specific ethanol yield (i.e. 10.5% or 13.5%) disclosed in the current invention are particularly obtainable from the use of α-amylase and glucoamylase as first and second starch hydrolyzing enzymes. Therefore, it is considered the current amendment introduced a new matter to the instant application.

In amended cases, subject matter not disclosed in the original application is sometimes

added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen,* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-16, 18-20, 31-36 and 45-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Seidman et al. (of the record) in view of Skory et al. (of the record).

Seidman et al. teach a process of liquefying starch derived from rice, tapioca, sorghum, potatoes, etc. (see column 5, lines 6-10) to a soluble hydrolysate using α-amylase at a temperature about 170°F-195°F, which is 76.7°C-90.5°C (see column 2, lines 46-60), and then a saccharification enzyme such as glucoamylase in the second step (see column 2, lines 8-12).

Seidman et al. teach that the saccharification product is dextrose-rich solution (col. 3, lines 55-60), and it is well known in the art that dextrose is a synonym of glucose, and thus, the

dextrose-rich solution of Seidman et al. is considered as glucose-rich syrup.

Seidman et al. do not teach the step for producing ethanol by fermentation with Aspergillus oryzae for 3 or 5 days (claims 45-50).

Skory et al. teach a fermentation process of simple sugars (glucose) using Aspergillus oryzae to produce ethanol (fermentation product) (see Table 1), and Skory et al. also show various duration of fermentation including 3-5 days and the yield of ethanol (see Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to use Aspergillus oryzae to ferment the glucose-rich syrup of Seidman et al. to produce fermentation product because it is well known in the art that Aspergillus oryzae is one of commonly used fungi in fermentation.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

Furthermore, it is well known in the art that saccharification and fermentation can be carried out simultaneously (also known as simultaneous saccharification fermentation; SSF), and Skory et al. also teach SSF for the production of ethanol using Aspergillus oryzae (p.203, left

col.). Since Seidman et al. utilize enzymes from Aspergillus oryzae (col. 5, lines 62-66) for saccharification, and the same microorganism can be used for fermentation of ethanol as taught by Skory et al., it would have been obvious to a person of ordinary skill in the art to use Aspergillus oryzae for saccharification as well as fermentation of ethanol using dextrose-rich solution of Seidman et al. in view of Skory et al.

With regard to the yield of ethanol being 10.5% or 13.5%, Seidman et al. in view of Skory et al. do not particularly teach the concentration. However, since it is well known in the art that the yield of ethanol from fermentation is variable based on the several parameters including amount of substrate (e.g. glucose), microorganism strains, duration of fermentation, etc., an artisan of ordinary skill in the art would have recognized that the yield of ethanol by using the method of Seidman et al. in view of Skory et al. would be routinely optimized.

Furthermore it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re* Aller, Lacey, and Haft, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re* Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931,24 USPQ 52; *In re* Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re* Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re* Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70

USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re* Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re* Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re* Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re* Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11,57 USPQ 136. (Emphasis added). With regards to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)).

Still further, the limitation of ethanol concentration having 10.5% or 13.5% is result from the method claimed in the current application. The limitation does not require any process step to be carried out other than disclosed in the current claims. Thus, the limitation does not limit the method of the current invention. Since the method steps of Seidman et al. in view of Skory et al. is substantially similar, if not identical, the results obtainable from the methods of Seidman et al. in view of Skory et al. is expected to be the same as the claimed invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651